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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/457,709	12/10/1999	RICHARD J. MELKER	U5583.0000/P	7980
7590 12/06/2004			EXAMINER	
David R. Saliwanchik			LEWIS, AARON J	
Saliwanchik, Lloyd & Saliwanchik, P.A. 2421 N.W. 41st Street, Suite A-1			ART UNIT	PAPER NUMBER
Gainesville, FL 32606-6669			3743	

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
	09/457,709	MELKER ET AL.	
Office Action Summary	Examiner	Art Unit	
	AARON J. LEWIS	3743	
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address	
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  If the period for reply specified above is less than thirty (30) days, a repl. If NO period for reply is specified above, the maximum statutory period.  Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be tin by within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).	
Status			
1) Responsive to communication(s) filed on 11/1	<u>9/2003 (AMENDMENT)</u> .		
	s action is non-final.		
3) Since this application is in condition for allowa			
closed in accordance with the practice under t	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.	
Disposition of Claims			
4) ☑ Claim(s) 37-85 is/are pending in the application 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☑ Claim(s) 37-85 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	wn from consideration.		
Application Papers			
9) The specification is objected to by the Examine		E cuitos	
10) The drawing(s) filed on is/are: a) acc			
Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct			
11) ☐ The oath or declaration is objected to by the E			
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bureat * See the attached detailed Office action for a list	its have been received. Its have been received in Applicat prity documents have been receiv au (PCT Rule 17.2(a)).	ion No ed in this National Stage	
Attachment(s)	_		
1) Notice of References Cited (PTO-892)	4) Interview Summary Paper No(s)/Mail D		
<ol> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date</li> </ol>	E) [ Nation of Informal	Patent Application (PTO-152)	

Art Unit: 3743

## **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 37-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanesaka (US 5042470) in view of Heinonen (US 5649531) & Haluszka et al, "Whole Body Plethysmography".

In regards to claims 37-85 Kanesaka substantially discloses the instant application's claimed invention to include the provision of a ventilator system (1/5) that contains a control device (Col. 4 lines 15-32, note the teaching of inputting of patient data into device that will facilitate ventilation, i.e. to control the device, therefore one of ordinary skill in the art would reasonably conclude that the device has a means for controlling its operation), with a means for inputting a data (note col. 4 lines 17-20) that provides ventilation to a patient and that may calculate ventilatory parameters utilizing such data which includes data that represents height, (i.e. put in a mixture of variables such as patient surface area based upon height & weight), but the teaching is unclear if the calculations are done in the control unit or by the operator and Kanesaka does not explicitly disclose use of height data alone to calculate a ventilatory parameter. However, Heinonen discloses an in situ control device rendering the respiratory ventilation control values (col. 8 lines 19-40) based upon data imputs. The references are analogous since they are from the same field of endeavor, the respiratory arts. At

Art Unit: 3743

the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Heinonen and used them with the device of Kanesaka. The suggestion/motivation for doing so would have been to relieve the operator of the burden of rendering the calculations and also minimizing the potential for human error by having the control device execute the calculations instead of the operator. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

The suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose solely using only patient height as the raw data to derive a ventilatory parameter. However, Haluszka disclose such (See the 5th paragraph on the first page of the English language abstract that starts with "It was stated") The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Haluszka and used them with the suggested device. The suggestion/motivation for doing so would have been to because patient body length alone can function as a sufficient ventilatory parameter/limitation predictor and all other raw data patient inputs improve correlation very little or are without practice influence (See paragraph 5 of the English language abstract of Haluszka). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art

Art Unit: 3743

would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Claims 38-47 define a plurality of ventilation parameters which are disclosed by Kanesaka (note col. 4 lines 15-32) as modified by Heinonen and/or Haluszka (note the tables and materials/methods sections) and/or such parameters would be mere obvious variables that one of ordinary skill in the art would appreciate as necessary to carry out any ventilatory methodology.

The balance of the claims 48-85 appear to be substantially equivalent in scope to claims 37-47 and are therefore rejected by the suggested device of Kanesaka, Heinonen & Haluszka as noted above which is herein incorporated by reference. With respect to the alarms of claim 66 and those claims that set forth the calculation/determination of a "ventilatory limit" note Kanesaka (Col. 4, line 5 et seq) which teaches a plurality of alarms which are responsive to the manually set ventilation parameters disclosed at col. 4, lines 16 et seq; these same parameters of the suggested device of Kanesaka, Heinonen & Haluszka are readable upon applicant's set forth "ventilatory limits" as one of ordinary skill in the art would appreciate such limits to be merely the points of the derived values wherein safe/proper ventilation wold not be affected and as such the operator/user should be notified and the control should respond/adjust ventilation.

Response to Arguments

1. Applicant's arguments, see page 3, filed 19 Nov 03, with respect to the rejection(s)of all claims under 35 USC 103 have been fully considered and are persuasive, and render all subsequent arguments moot. Therefore, the rejection has been modified to clearly set forth the examiner's position on what the prior art does &

Art Unit: 3743

does not set forth and how the mesh under 35 USC 103 in light of the current level of one of ordinary skill in the art and the current claim language. Accordingly, the rejection is made non-final so that applicant has full benefit of an accurate and consistent analysis of the prior art that is a proper reasoned basis IAW 5 USC 555 for informal adjudication and the relevant substantive patent law. Accordingly for this reason, and for only this reason and for no other reason is this action being made non-final.

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Aaron J. Lewis Primary Examiner

1/29/04